

SENATE BILL 1706
By Ford

AN ACT to amend Tennessee Code Annotated, Title 56,
relative to health insurance coverage related to
certain clinical trials.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, Part 23, is amended by
adding the following as a new section:

56-7-2365.

(a) For purposes of this section:

(1) "Health benefit plan" means any hospital or medical expense
policy, health, hospital or medical service corporation contract, a policy or
agreement entered into by a health insurer or a health maintenance
organization contract, other plans administered by the state government,
or any certificate issued under any such policies, contracts or plans.

(2) "Health insurer" means any entity offering a health benefit plan
as defined in subdivision (1);

(3)

(A) "Routine patient care costs" means the costs associated
with the provision of health care services, including drugs, items,
devices, and services that would otherwise be covered under the
plan or contract if those drugs, items, devices, and services were
not provided in connection with an approved clinical trial program,
including:

(i) Health care services typically provided absent a clinical trial;

(ii) Health care services required solely for the provision of the investigational drug, item, device, or service;

(iii) Health care services required for the clinically appropriate monitoring of the investigational item or service;

(iv) Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service; and

(v) Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.

The subject of the trial must evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage.

(B) For purposes of this section, “routine patient care costs” does not include the costs associated with the provision of any of the following:

(i) Drugs or devices that have not been approved by the federal food and drug administration and that are associated with the clinical trial;

(ii) Services other than health care services, such as travel, housing, companion expenses, and other nonclinical expenses, that an enrollee may require as a result of the treatment being provided for purposes of the clinical trial;

(iii) Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient;

(iv) Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee's health plan;

(v) Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial; or

(vi) Items or services provided solely to determine trial eligibility.

(b) For an enrollee diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every health benefit plan that is issued, amended, delivered, or renewed in this state, shall provide coverage for all routine patient care costs related to the clinical trial if the enrollee's treating physician, who is providing covered health care services to the enrollee under the enrollee's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential benefit to the enrollee. For purposes of this

section, a clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.

(c) The treatment shall be provided in a clinical trial that either:

(1) Involves a drug that is exempt under federal regulations from a new drug application; or

(2) Is approved by one of the following:

(A) One of the national institutes of health;

(B) The federal food and drug administration, in the form of an investigational new drug application;

(C) The United States department of defense; or

(D) The United States veterans' administration.

(d) In the case of health care services provided by a participating provider, the payment rate shall be at the agreed-upon rate. In the case of a nonparticipating provider, the payment shall be at the negotiated rate the plan would otherwise pay to a participating provider for the same services, less any applicable copayments and deductibles.

(e) Nothing in this section shall be construed to prohibit a health care service plan from restricting coverage for clinical trials to participating hospitals and physicians in this state unless the protocol for the clinical trial is not provided for at a state hospital or by a state physician.

(f) The provision of services when required by this section shall not, in itself, give rise to liability on the part of the health care service plan.

(g) Nothing in this section shall be construed to limit, prohibit, or modify an enrollee's rights to the independent review process available or to the independent medical review system.

(h) Nothing in this section shall be construed to otherwise limit or modify any existing requirements under the provisions of this chapter or to prevent application of copayment or deductible provisions in a plan.

(i) Copayments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services If not delivered in a clinical trial.

(j) The provision of services when required by this section shall not, in itself, give rise to liability on the part of the insurer.

(k) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance, except that for specified disease and hospital indemnity insurance, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section shall be construed as imposing a new benefit mandate on specified disease or hospital indemnity insurance.

SECTION 2. This act shall take effect July 1, 2005, the public welfare requiring it. This act shall apply to contracts entered into or renewed on and after July 1, 2005.